

### **REMARKS**

This is a response to the Office Action dated September 13, 2006, (hereinafter the “Office Action”). Claim 1 has been amended. Upon entry of this amendment, claims 1-5, 7, 9-20 and 38-41 will be pending in the present application.

Independent claim 1 has been amended to limit the method to treatment of radiation injury due to one or more types of radiation selected from the group consisting of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

### **Provisional Obviousness-Type Double Patenting Rejections**

Claims 1, 4-9 and 12-20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending U.S. Patent application no. 10/288,761. Although the applicant does not concede the correctness of this objection, a terminal disclaimer is enclosed herewith in order to obviate this rejection and expedite prosecution of the present application.

Claims 1, 4-9 and 12-20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending U.S. Patent application no. 10/279,315. In the previous two responses, the applicant already indicated that U.S. Patent application no. 10/279,315 has become abandoned. Accordingly, withdrawal of this rejection is again requested for this reason.

### **The Obviousness-Type Double Patenting Rejection**

Claims 1-5, 16-20 and 38-41 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,753,325. Although the applicant does not concede the correctness of this objection, a terminal disclaimer is enclosed herewith in order to obviate this rejection and expedite prosecution of the present application.

### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-4, 7, 9-20, 38 and 39 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,162,801, issued to Kita (hereinafter “Kita”), Bissett, D.L. *et al.*, *J. Soc. Cosmet. Chem.* **1992**, 43, 85-92 (hereinafter “Bissett”), and Darr, D. *et al.*, *British Journal*

of *Dermatology* **1992**, 127, 247-253 (hereinafter “Darr”), in view of Shimoi, K., *et al.*, *Mutation Research* **1996**, 350, 153-161 (hereinafter “Shimoi”) and U.S. Patent No. 5,776,460, issued to Kim et al. (hereinafter “Kim”). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

First, the Examiner has not made out a case of *prima facie* obviousness since:

- (a) Kita does not disclose oral administration of a composition, as required by the claims,
- (b) Kita uses vitamin D<sub>3</sub> as a sunblock to absorb UV radiation and thus does not teach the effectiveness of vitamin D<sub>3</sub> against radiation injury if the vitamin D<sub>3</sub> were orally ingested,
- (c) The claims do not claim use of the materials taught by Bissett,
- (d) The claims do not claim use of the materials taught by Darr et al.,
- (e) The claims do not claim use of the materials taught by Shimoi et al.,
- (f) The claims do not claim use of the materials taught by Kim et al., and
- (g) None of the cited references specifically refers to treatment of an injury caused by a radiation selected from the group consisting of one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

Based on the teachings of Kita, a skilled person would not employ vitamin D compounds as a blocking agent against any type of radiation selected from the group consisting of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation. This is because Kita relies on absorption of radiation by the vitamin D compounds and Kita clearly teaches that vitamin D compounds absorb radiation in the 240-290 nm range. See col. 1, lines 25-29, col. 6, lines 17-29 and col. 8, lines 49-62 of Kita. As a result, vitamin D compounds would not be considered useful as a blocking agent against the claimed types of radiation since none of the claimed types of radiation has a wavelength of 240-290 nm and thus none of the claimed types of radiation would be absorbed by topical application of vitamin D compounds, as taught by Kita.

In addition, it is clear from the teachings of Kita, that Kita is only concerned with UV radiation since Kita only discusses injury caused by UV radiation in the wavelength ranges of 200-315 nm, which is far outside the wavelength range of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation. The energies of the various types of radiation are given below:

<b><u>Radiation Type</u></b>	<b><u>Energy</u></b>
Ultraviolet radiation	1.24 eV-124 eV
Gamma radiation	124 keV-1.24 MeV
Fluoroscopic radiation (X-ray radiation)	124 eV-124keV

Also, clearly alpha radiation (alpha particles), beta radiation (beta particles) and proton radiation (protons) is different from ultraviolet radiation.

In the Examiner's Response to Arguments on page 10 of the Office Action, the Examiner first took the position that applicant's argument that Kita et al. does not teach the use of vitamin D compounds as blocking agents against the types of radiation claimed was not persuasive since the wavelength range of UV radiation of 40-124 nm is not found in the claims. As shown above, the present claims, as amended, are now limited to damage caused by specific types of radiation. Thus, the claims exclude ultraviolet radiation since (1) ultraviolet radiation is not alpha, beta or proton radiation, and (2) ultraviolet radiation has a different energy (and thus also wavelength) than gamma radiation and fluoroscopic radiation. Thus, there is clearly no overlap between the types of radiation claimed and ultraviolet radiation as disclosed in Kita et al. Accordingly, the claims, as amended, clearly support the applicant's position that Kita et al. does not teach or suggest to the skilled person to treat damage caused by any of the types of radiation that are currently claimed.

The Examiner also took the position in the Response to Arguments on page 10 of the Office Action that the claim language "comprising" which appeared before the list of the types of radiation is open-ended. Claim 1 has been amended to replace "comprising" with the closed claim language, "selected from the group consisting of" in order to address this objection raised by the Examiner. It is considered that this amendment to claim 1 limits the claim to treatment of a radiation injury caused by one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

The Examiner also takes the position on page 10 of the Office Action that, "Whether or not Kita meant for this oral administration to be applicable for treating radiation injury or other diseases is immaterial, as long as oral administration is disclosed." The applicant disagrees with this conclusion. The Examiner has the burden of making out a case of *prima facie* obviousness. The claims require oral administration of vitamin D for the purpose of treating radiation injury.

Thus, for Kita et al. to form the basis for a case of *prima facie* obviousness, Kita et al. must teach a skilled person to orally administer vitamin D for the purpose of treating radiation injury. The fact that the Examiner's position is incorrect is confirmed by the fact that if the only requirement were that Kita et al. teach oral administration of vitamin D, then all methods of orally administering vitamin D for any purpose would be obvious and therefore unpatentable. This clearly conflicts with MPEP §2143.03, "All Claim Limitations Must Be Taught or Suggested" which reads,

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

In the present case, the claim limitation of treating radiation injury by oral administration of vitamin D is not taught or suggested by Kita et al.

Moreover, Kita teaches topical use of vitamin D compounds to absorb UV radiation. The UV radiation is absorbed because the vitamin D compounds are located between the body and the source of radiation. The present claims relate to oral administration of the composition, in which case the vitamin D<sub>3</sub> is not located between the source of radiation and the body. As a result, the skilled person would have no expectation of success for oral administration of vitamin D<sub>3</sub> from the teachings of Kita. That Kita is limited to topical application of vitamin D compounds is confirmed by the title of Kita, which reads, "**External** Ophthalmic Preparation Containing Vitamin D."

Kita, in summarizing the prior art, mentions that therapeutic vitamin D may be administered orally or by injection. See col. 1, lines 42-44 of Kita. However, the prior art oral administration is not for the purpose of treating radiation injury, but rather, is for the purpose of treating one or more of, "...rickets, osteomalacia, osteoporosis, osteitis, fibrosa, osteosclerosis and other bone diseases, malignant tumors such as breast and colon cancers..." See col. 1, lines 15-24 of Kita. Again, this provides the skilled person with no teaching or suggestion that oral administration of vitamin D would have any beneficial effect in the treatment of radiation injury. From this, it is clear that Kita does not teach or suggest the internal administration of Vitamin D, as in the present invention.

Accordingly, favorable consideration and withdrawal of the rejection is requested.

Claims 5 and 39-41 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,162,801, issued to Kita (hereinafter "Kita"), Bissett, D.L. *et al.*, *J. Soc. Cosmet. Chem.* **1992**, 43, 85-92 (hereinafter "Bissett"), and Darr, D. *et al.*, *British Journal of Dermatology* **1992**, 127, 247-253 (hereinafter "Darr"), in view of Shimoi, K., *et al.*, *Mutation Research* **1996**, 350, 153-161 (hereinafter "Shimoi"), U.S. Patent No. 5,776,460, issued to Kim *et al.* (hereinafter "Kim"), and further in view of U.S. Patent no. 5,141,741 (Ishida *et al.*) and U.S. Patent no. 5,650,137 (Nguyen *et al.*). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

(a) None of the cited references specifically refers to treatment of an injury caused by one or more types of radiation selected from the group consisting of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

(b) Kita, Nguyen *et al.* and Ishida *et al.* do not disclose oral administration of a composition, as required by the claims,

(c) Kita uses vitamin D<sub>3</sub> as a sunblock to absorb UV radiation and thus does not teach the effectiveness of vitamin D<sub>3</sub> against radiation injury if the vitamin D<sub>3</sub> were orally ingested,

(d) Nguyen *et al.* and Ishida *et al.* use antioxidants to treat skin, scalp and mucosa by topical application directly to the area to be treated and thus do not give any indication of an expectation of success via oral administration of antioxidants,

The claims do not claim use of the materials taught by Bissett,

(d) The claims do not claim use of the materials taught by Darr *et al.*,

(e) The claims do not claim use of the materials taught by Shimoi *et al.*,

(f) The claims do not claim use of the materials taught by Kim *et al.*, and

This rejection should be withdrawn for several reasons. First, the primary reference to Kita, which is the only reference relating to the use of vitamin D<sub>3</sub>, does not teach or suggest use of vitamin D<sub>3</sub> to treat an injury caused by one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation. Instead, Kita relates to the use of vitamin D<sub>3</sub> as a sunblock to absorb UV radiation. This is significant because the claimed types of radiation are significantly different from UV radiation, as discussed above. Thus, a skilled person would not consider treatments for UV radiation to be applicable to injuries due to the

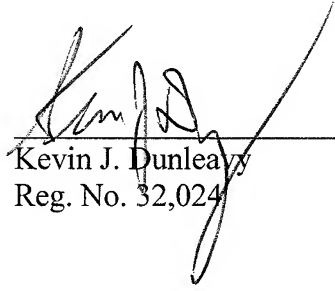
claimed types of radiation since there is no reason to expect a successful result from the treatment.

Nguyen is clearly concerned with exposure to atmospheric ultraviolet radiation that causes skin ageing. See e.g. col. 1, lines 18-26 of Nguyen where Nguyen states, “These harmful effects are exerted in particular on the cells of the skin and of the mucous membranes in contact with the external environment.” (emphasis added). Col. 5, lines 25-54 of Nguyen also relate to this point. The same is true of Ishida, et al., which is entitled, “Anti-Sunburn Skin-Care Preparation.” Thus, the skilled person would not apply the teachings of Ishida et al. or Nguyen et al. in the present invention for at least two important reasons. First, the type of injury caused by the claimed types of radiation, proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation is different from the skin injury caused by UV radiation, as discussed in the applicant’s submission of January 21, 2005, and thus the skilled person would not conclude that a treatment for UV radiation would be effective to treat an injury due to the claimed forms of ionizing radiation.

Second, Ishida et al. and Nguyen et al. only relate to the treatment of the skin, scalp and/or mucosa. The present invention requires oral administration of the composition. The skilled person would not conclude that a skin, scalp and/or mucosa treatment would be effective if administered orally. Stated otherwise, skilled persons would not ingest topical compositions with the expectation of successfully treating ionizing radiation injury since there is no indication in these references that the compositions would be effective if they were not applied in direct contact with the area to be treated, e.g. skin, scalp or mucosa. For example, skilled persons clearly do not ingest sunscreen with the expectation that it will prevent sunburn.

For the foregoing reasons, favorable consideration and withdrawal of the rejection under 35 U.S.C. 103(a) and issuance of a Notice of Allowance are requested.

Respectfully submitted,



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